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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BABIC, CHRISTOPHER M

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/500,435	Applicant(s) KAMATA ET AL.	
	Examiner Christopher M. Babic	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 14-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/20/04; 8/30/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 1, Claims 1-13, and *M. tuberculosis*, readable on Claim 11, in the reply filed on February 13, 2006 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 5-7, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Robson et al. (EP 0 547 789 A1).

With regard to Claim 1, Robson et al. teach a method of lysing an acid-fast bacterium to extract a gene from the acid-fast bacterium (Abstract; Pages 6,7,11, for example) comprising: heating the acid-fast bacterium (Page 6, Line 55-Page 7, Line 5, for example) in a liquid containing a non-ionic detergent (Page 7, Lines 20-35, for example) at a temperature below a boiling point of the liquid (Page 6, Line 55-Page 7, Line 5, for example).

With regard to Claim 2, Robson teaches a heating temperature not less than 70°C and less than 100°C (Page 6, Line 55-Page 7, Line 5, for example).

With regard to Claim 3, Robson teaches heating performed for 1 to 30 minutes (Page 7, Lines 20-25, for example).

With regard to Claim 5, Robson teaches a pH of the liquid is in a range from 7.0 to 12.0 (Page 7, Lines 25-35, for example).

With regard to Claim 6, Robson teaches a concentration of the non-ionic detergent in the liquid is 0.01 to 10 wt% (Page 7, Lines 25-35, for example).

With regard to Claim 7, Robson teaches Tween 20 (Page 7, Lines 25-35, for example).

With regard to Claim 11, Robson teaches *M. tuberculosis* (Page 7, Lines 50-60, for example).

With regard to Claim 12, Robson teaches acid-fast bacterium selected from sputum (Page 7, Lines 35-45, for example).

With regard to Claim 13, Robson teaches the subsequent amplification of a gene extracted from a sample (Page 7, Lines 10-20, for example).

2. Claims 1-3, 5, 6, and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Britschgi et al. (U.S. 5,712,095).

With regard to Claim 1, Britschgi et al. teach a method of lysing an acid-fast bacterium to extract a gene from the acid-fast bacterium (Column 4, Lines 25-35;

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Column 6, Lines 40-55; Columns 7,8, for example) comprising: heating the acid-fast bacterium (Column 8, Lines 50-55, for example) in a liquid containing a non-ionic detergent (Column 8, Lines 35-50, for example) at a temperature below a boiling point of the liquid (Column 8, Lines 50-55, for example).

With regard to Claim 2, Robson teaches a heating temperature not less than 70°C and less than 100°C (Column 8, Lines 50-55, for example).

With regard to Claim 3, Robson teaches heating performed for 1 to 30 minutes (Column 7, Lines 35-40, for example).

With regard to Claim 5, Robson teaches a pH of the liquid is in a range from 7.0 to 12.0 (Column 8, Lines 35-50, for example).

With regard to Claim 6, Robson teaches a concentration of the non-ionic detergent in the liquid is 0.01 to 10 wt% (Column 8, Lines 35-50, for example).

With regard to Claim 8, Robson teaches a metal chelating agent (Page 7, Lines 25-35, for example).

With regard to Claim 9, Robson teaches a concentration of a metal chelating agent of 0.1 to 100mM (Column 7, Lines 35-55, for example).

With regard to Claim 10, Robson teaches EDTA (Column 7, Lines 35-55, for example).

With regard to Claim 11, Robson teaches *M. tuberculosis* (Page 7, Lines 50-60, for example).

With regard to Claim 12, Robson teaches acid-fast bacterium selected from sputum (Page 7, Lines 35-45, for example).

With regard to Claim 13, Robson teaches the subsequent amplification of a gene extracted from a sample (Page 7, Lines 10-20, for example).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robson et al. (EP 0 547 789 A1) in view of Pierre et al. ("Use of a reamplification protocol improves sensitivity of detection of Mycobacterium tuberculosis in clinical samples by amplification of DNA" J Clin Microbiol. 1991 Apr;29(4):712-7).

With regard to Claim 4, the methods of Robson have been outlined in the above rejections. Robson teaches optimization of the heating temperatures and times during cell lysis (Page 6, Lines 55-60; Page 7, Lines 20-25, for example), however, does not expressly teach a heating step of 96°C for 10 minutes.

Pierre et al. expressly teach the successful extraction of DNA from mycobacterium including heating the sample in a non-ionic detergent at 95°C for 10 minutes.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify Robson to optimize the heating temperatures and times since Robson expressly suggests such an optimization and Pierre expressly teaches nearly the same parameters. Also, an ordinary practitioner would have recognized that the optimizable variables of heating temperature and time could be adjusted to maximize the desired results. As noted in *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of specific times or primer concentrations for amplification was other than routine or that the results should be considered unexpected in any way as compared to the closest prior art.

2. Claims 4 and 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Britschgi et al. (U.S. 5,712,095) in view of Pierre et al. ("Use of a

reamplification protocol improves sensitivity of detection of Mycobacterium tuberculosis in clinical samples by amplification of DNA" J Clin Microbiol. 1991 Apr;29(4):712-7).

With regard to Claim 4, the methods of Britschgi have been outlined in the above rejections. Britschgi teaches optimization of the heating temperatures and times during cell lysis (Column 8, Lines 50-55, for example), however, does not expressly teach a heating step of 96°C for 10 minutes.

Pierre et al. expressly teach the successful extraction of DNA from mycobacterium including heating the sample in a non-ionic detergent at 95°C for 10 minutes.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify Britschgi to optimize the temperatures and times since Britschgi expressly suggests such an optimization and Pierre expressly teaches nearly the same parameters. Also, an ordinary practitioner would have recognized that the optimizable variables of heating temperature and time could be adjusted to maximize the desired results. As noted in *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of specific times or primer concentrations for amplification was other

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than routine or that the results should be considered unexpected in any way as compared to the closest prior art.

With regard to Claim 8, Pierre teaches Tween-20 and Triton-X 100 (Page 713, Column 1, for example).

Conclusion

Claims 1-13 are rejected. No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Folgueira et al. "Detection of Mycobacterium tuberculosis DNA in clinical samples by using a simple lysis method and polymerase chain reaction" J Clin Microbiol. 1993 Apr;31(4):1019-21.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



3/22/06

Christopher M. Babic
Patent Examiner
AU 1637



KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

3/27/06